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09/872,526	06/01/2001	Peter M. Bonutti	BON-1360-7	3309

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PAUL D. BIANCO
Fleit Gibbons Gutman Bongini & Bianco PL
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

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08/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	09/872,526		BONUTTI, PETER M.	
	Examiner		Art Unit	
	Anu Ramana		3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38-50,52-55 and 57-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38-50,52-55 and 57-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 41, 42 and 54 are objected to because of the following informalities.

In claims 41 and 42, "wherein the irrigation and suction" should be "wherein the step of irrigating and the step of applying suction alternate."

In claim 54, line 2, it appears that "fiber option" should be "fiber optic."
Appropriate correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. Applicant's specification does not provide antecedent basis for the limitations of claim 36, namely, "obtaining fetal tissue in utero while maintaining viability of the fetus and of the fetal tissue obtained", and claim 65, " wherein the fetus is the patient." See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36, 38-50, 52-55 and 57-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 36, Applicant's disclosure as originally filed does not provide support for "obtaining fetal tissue in utero while maintaining viability of the fetus and the fetal tissue obtained, said method comprising the steps of cutting the fetal tissue from the fetus." A

detailed description is provided under the "Response to Arguments" section of this office action.

In claim 65, Applicant's disclosure as originally filed does not provide support for "wherein the fetus is the patient." A detailed description is provided under the "Response to Arguments" section of this office action.

Claims 36, 38-50, 52-55 and 57-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claim 36, the specification does not provide support for how viability of the fetal tissue is maintained. For examination purposes, the Examiner is assuming any procedure that does not excessively manipulate the tissue during extraction to meet this limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 38-50, 52-55 and 57-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how viability of the fetal tissue obtained is maintained.

In claim 54, line 2, the recitation, "at least one of the steps of cutting and implanting" renders the claim vague and indefinite since "and implanting" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 38, 39, 54, 57, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (US 4,756,708).

Martin discloses a method of obtaining fetal tissue in utero while maintaining viability of the fetus and the fetal tissue obtained including the steps of: by cutting or separating fetal tissue from the fetus by inserting an obturator through a "biopsy catheter" or flexible apparatus and moving the fetal tissue along the hollow interior of the catheter or passage by applying suction (col. 4, lines 4-39).

Regarding claim 38, Martin discloses rotating motion being used to disconnect the obturator, prior to application of suction (col. 4, lines 12-15).

Regarding claim 39, Martin clearly discloses the use of reciprocating motion, namely, insertion followed by withdrawal, of both the flexible catheter and the obturator.

Regarding claim 54, Martin also discloses using an ultrasonic guiding apparatus to guide the obturator through the flexible catheter or endoscope (col. 4, lines 4-39).

Regarding claim 57, Martin discloses a flexible shaft 28 and a drive means 50 for pushing and pulling obturator 30 (Fig. 3, col. 3, lines 30-65). It is noted that Martin discloses obturator 30 to have a tip or "cutting tip" 56 that is moved by drive means 44. It has been held that to be entitled to weight in method claims, the recited structural limitations therein must affect the method in a manipulative sense, and not amount to the mere claiming of a use of particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

Regarding claim 58, Martin discloses application of suction by attaching a vacuum tube or syringe to shaft 28.

Regarding claim 59, Martin discloses the flexible shaft to have a flexible outer member 28 and a flexible inner member 54 (Figs. 2-3).

Claims 36, 40-42, 44 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Golbus MS, McGonigle KF, Goldberg JD, et al: Fetal tissue sampling - The San Francisco Experience with 190 Pregnancies," West J Med 1989 Apr; 150: 423-430 (or "Golbus" herein).

Golbus discloses extracting a fetal tissue sample in utero, for e.g., liver tissue, under sonographic or endoscopic guidance wherein a needle is used to penetrate or cut tissue, followed by attachment of a syringe to the needle, with application of negative pressure or suction to draw tissue into the syringe (page 423 and 424).

Regarding claims 40 and 42, Golbus discloses extracting tissue using suction, immediately followed by, i.e., substantially simultaneously, including the step of irrigating the tissue using saline. It is noted that on page 423, Golbus discloses flushing liver tissue from the needle by application of saline solution.

Regarding claim 41, Golbus discloses obtaining additional specimens to provide sufficient tissue. It is the Examiner's position that extraction of one specimen (including one step of applying suction and irrigation) followed by extraction of another specimen (including another step of applying suction and irrigation) inherently includes alternating steps of suction and irrigation.

Regarding claim 44, Golbus discloses centrifuging the extracted tissue to differentiate extracted tissue from blood contamination.

Regarding claim 54, Golbus discloses the use of a fetoscope or endoscope for obtaining the fetal tissue sample.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 4,756,708) in view of Siegmund (US 4,598,698).

Martin discloses all elements of the claimed invention except for the use of suction in conjunction with irrigation to perform a biopsy.

It is well known to use suction in conjunction with irrigation for tissue retrieval during a biopsy procedure as evidenced by Siegmund. Siegmund teaches a device to perform biopsies including suction and irrigation channels for tissue retrieval (col. 2, lines 22-68, col. 3 and col. 4, lines 1-7).

The substitution of one known biopsy device (as taught by Siegmund) for another known biopsy device (as disclosed by Martin) would have been obvious to one of ordinary skill in the art at the time of the invention since this amounts to simple substitution of one known device for another and would have yielded predictable results, namely, tissue retrieval during a biopsy procedure.

The method steps of claims 40-42 are rendered obvious when then method of Martin is conducted using the device of Siegmund for fetal tissue retrieval.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 4,756,708) in view of Molomut et al. (US 3,224,434).

Martin discloses all elements of the claimed invention except for the use of a syringe with a built-in filter for collection of tissue fragments or cells.

Molomut et al. teach the use of a syringe with a built-in filter such that when suction is applied to collect tissue fragments or cells, the filter traps the cells for subsequent analysis (col. 2, lines 25-72 and col. 3, lines 1-39).

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of a syringe with a built-in filter, as taught by Molomut et al., to the Martin procedure would have yielded predictable results, i.e., enhanced collection of cells for subsequent analysis.

The method steps of claim 43 are rendered obvious when suction is applied in the method of Martin, using a syringe with a built-in filter, as taught by Molomut et al., for separation of fetal tissue from biological fluids.

Claims 38-40, 42-43 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 4,756,708) in view of Weaver (US 4,245,653).

Martin discloses all elements of the claimed invention except for: (1) the use of irrigation and suction for tissue retrieval; and (2) the use a flexible apparatus including a flexible inner member and an outer member wherein the outer member is more rigid than the inner member.

Weaver teaches a device for obtaining endometrial tissue samples including: a rigid outer member (12, 16), the outer member being rigid in that it has a fixed shape; and a flexible or bendable inner member 22 with a cutting tip wherein irrigation and suction is applied to the passage between the inner and outer members to extract severed tissue. Weaver also teaches the use of rotating motion to cut tissue (col. 2, lines 53-68, col. 3, lines 1-40 and lines 54-68 and col. 4, lines 1-26).

Regarding claim 39, Weaver teaches the use of reciprocating motion, namely, insertion followed by withdrawal of the apparatus, of both the flexible catheter and the obturator.

Regarding claim 43, Weaver teaches the use of filtration to separate collected tissue from the irrigation fluid.

The substitution of one known tissue retrieval device (as taught by Weaver) for another known biopsy device (as disclosed by Martin) would have been obvious to one of ordinary skill in the art at the time of the invention since this amounts to simple substitution of one known device for another and would have yielded predictable results, namely, tissue retrieval during a biopsy procedure.

The method steps of claims 38-40, 42 and 57-61 are rendered obvious when the method of Martin is conducted using the device of Weaver for tissue retrieval.

Claims 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golbus in view of O'Neill (US 4,986,279).

Golbus discloses all elements of the claimed invention except for a performing the method steps under X-ray or ultrasound guidance.

The use of X-ray or ultrasound guidance for imaging the placement of a cannula or needle is well known in the art, as evidenced by O'Neill (col. 6, lines 25-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized X-ray or ultrasound guidance for placement of the Golbus et al. needle, as taught by O'Neill, for visualization of the distal tip of the needle for proper placement of the needle.

The method steps of claim 52 are rendered obvious by the above discussion.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on February 21, 2008 have been considered but are moot in view of the new ground(s) of rejection.

Regarding Applicant's arguments on page 5, that there is support for "maintaining the viability of the fetus" and on page 6 that "the express intent throughout the specification is to avoid damage to both the donor and the tissue removed from the donor," the Examiner notes that express intent is not the standard by which a determination of compliance with 35 U.S.C. 112, first paragraph is made.

For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of the invention.

Turning to Applicant's specification, the only language pertinent to the method steps of claims 36, 63 and 65 are:

At page 3, lines 5-12: "and to avoid vital tissue which could otherwise be in the cutting path. For example, when removing unwanted tissue inside a knee joint the drill

shaft can deform, and is therefore less likely to damage normal tissue or joint surfaces. None of these functions is possible with a straight line system."

At page 3, lines 18-20: "The invention is not limited to the removal of bone tissue and may be used for removal of cartilage, muscle, fetal tissue etc."

At page 7, lines 7-14: "Thus, the tissue fragments are not merely removed from the body and may be harvested for implantation of the fragments, preferably, into the body of the patient from whom they are removed."

At page 8, lines 3-6: "Human tissue grafting works best using the patient's own tissue as donor material. Therefore, the harvested tissue may be implanted in the donor's own body for grafting."

At page 9, lines 5-11: "The method may further include the step of controlling the location of the cutting tip within the tissue with a guide rod, the step of collecting one or more selected components of the harvested tissue fragments, and/or the step of implanting the fragments into the body of the patient from whom they were removed."

At page 11, lines 20-24: "It should be understood that the present invention is not limited to the removal of bone tissue, but is useful in the removal of any hard or soft tissue in the body such as excess, unwanted, or tumorous tissue or tissue used for reimplantation or grafting."

At page 21, lines 7-14: "The harvested tissue fragments are not merely removed from the body of the patient, but are also collected in the structure 28 and thus harvested or saved for later implantation of the fragments, for later implantation of the fragments, preferably into the body of the patient from whom they are removed. Such harvesting and implantation are desirable because human tissue grafting works best using the patient's own tissue as donor material."

It is the Examiner's position that the above disclosure does not provide support for the recitation, "obtaining fetal tissue in utero while maintaining viability of the fetus and of the fetal tissue obtained." Further, Applicant's disclosure as originally filed does not identify who the patient is - the fetus or the person carrying the fetus.

Accordingly, it is deemed that the amendment filed on February 21, 2008 introduces new matter, necessitating the rejections made in this office action under 35 USC 112 first and second paragraphs.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
August 20, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3733